

REMARKS

Reconsideration of this application, and allowance of the claims is respectfully requested.

The amendment to claims 1, 6, and 11 is clearly supported by the specification and drawings. Vent (or purge) aperture 50 clearly communicates with the inflation lumen. The inflation lumen, as stated on pages 7 and 8 of the specification, comprises the "passageway between the inner tubular member 10 and the outer tubular member 4..." Reference numeral 50 is shown in Figs. 1 and 2.

The examiner has rejected claims 11-14 as unpatentable over the combination of Shimada et al. U.S. Patent No. 4,819,751, further in view of Rydell U.S. Patent No. 4,811,737 and Burns et al. 5,176,698.

The examiner notes the presence of "vent 35" of the catheter outer wall in Shimada et al., which relates to a balloon catheter. However, the examiner is urged to consider the language of the last paragraph of claim 11: "...at least one vent aperture for purging air from said inflation lumen, said aperture extending radially through the outer wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon."

When one considers "vent 35" of Shimada et al., it is clear that this claim language is not met. There is indeed an infusion port 35, which communicates with an infusion lumen 19, for providing solution to the area exterior of the balloon. However, there is no way that inflation or deflation of the balloon can be controlled by any flow of fluid through "vent" 35! Instead, it can be seen that inflation of the Shimada et al. balloon is controlled through the annular space between catheter body 13 and inner tube 40 in a manner which is generally conventional per se, and not influenced by

infusion port 35, which is in a separate flow path. Accordingly, it is clear that the language of the last three lines of claim 11 is not met from any disclosure of Shimada et al.

The examiner raises Rydell as a disclosure of the specific size of venting ports in a balloon catheter.

The size of the holes is extremely small, as taught both in Rydell and this present invention. However, in Rydell, the holes are positioned within the balloon or expander member itself, while, as claimed in this invention, such as claim 11, the vent aperture is not carried within the balloon, but, rather, is carried on the "...outer wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon."

More predictable results of venting can be provided when the venting aperture is placed on a stable, non-expanding structure such as the outer tubular member of this invention rather than the inner tube 12 surrounded by the balloon. The inner tube 12 receives a guidewire, which can block venting flow and thus interfere with operation of the catheter of Rydell.

Accordingly, it is submitted that Rydell also fails to render claim 11 obvious, particularly the last three lines thereof.

Turning to the examiner's discussion of Burns et al., while the examiner states that Burns discloses a gas permeable balloon, it is submitted that Burns does not specifically disclose a gas permeable balloon. Rather, Burns discloses various passageways to permit venting of a balloon, which has an intact, unperforated surface.

Accordingly, while applicant's attorney does not deny the fact that it is known that balloons can have various rates of gas permeability, it is submitted that Burns et al. does not stand for that proposition.

Accordingly, when claim 11 and its dependent claims are considered in light of a combination of the three cited references: Shimada et al., Rydell, and Burns et al., it is submitted that any combination of these references fails to disclose or render obvious particularly the last three lines of claim 11. As such, it is believed that claim 11 and its dependent claims are patentable over these references.

The examiner has also rejected claims 11 through 14 as unpatentable over Jang U.S. Patent No. 4,744,366, further in view of Rydell U.S. Patent 4,811,737, and Burns et al. 5,176,698.

Jang discloses a balloon catheter. Particularly, the examiner refers to vent 36, which the Jang patent refers to as "holes 36". These holes work together with holes 40 and, as stated in Jang, column 12, lines 22, *et. seq.* that "...holes 36, 40 preferably are connected only to the central lumen and do not interrupt any other lumen. Thus, these holes provide a means for permitting the flow of blood through the catheter shaft past the balloons 16, 20. The provision of holes 36, 40 to permit blood to bypass the balloons is important in angioplasty procedures in which it is desirable to prevent occlusion of the blood vessel during the positioning, inflation, deflation, and removal of the balloons."

Accordingly, clearly, Jang also fails to disclose the concept of a "vent aperture for purging air from said inflation lumen..." In the above quoted portion from Jang, it is

clearly stated that holes 36 and 40 avoid connection with the inflation lumen! Thus, obviously, they could not be used for purging air from the inflation lumen.

Turning again to Rydell, as previously stated that patent discloses a slit, or an extremely small hole which is formed in the inner tube 12 inside of balloon 20 for purposes of venting air while minimizing outflow of liquid.

The examiner is urged to note that this fails to describe the last three lines of claim 11, which calls for "...at least one vent aperture for purging air from said inflation lumen, said aperture extending radially through said outer wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon."

In Rydell, the slit or hole 26 is positioned in the wall of an inner tube within the balloon. In this invention, as claimed, the vent aperture is positioned in an outer wall of an outer tubular member at a location spaced from the balloon.

By this invention, as described in the specification, the vent aperture is primarily for purging air from the catheter body. Air is purged directly by diffusion through the wall of the balloon, as taught by this invention, with the balloon material having some gas permeability to allow this result. See the bridging paragraph of pages 12 and 13 of the specification.

Turning to Burns, it is submitted that Burns uses vents to remove air from the balloon, and does not teach the use of air removal through the gas permeability of the balloon. If the examiner disagrees, he is requested to provide the exact citation in Burns et al. that supports this teaching. Note for example Burns, column 2, lines 25-27.

Accordingly, it is submitted that the three references, in combination, fail to disclose the subject matter of claim 11 and its dependent claims, particularly the last three lines of claim 11.

The examiner has also rejected claims 1-16 as unpatentable over Jang, Burns et al. and Rydell as applied to claims 11-14, further in view of Carlblom U.S. Patent No. 5,637,365 and Follmer et al. 5,728,085.

Each of the independent claims of this application, as amended, namely claims 1, 6, and 11, have at last three lines providing the same distinction, previously discussed with respect to claim 11, and are submitted to provide patentable distinction over any combination of Jang, Burns et al., and Rydell.

Follmer et al. is cited for the use of constraining member 200 to limit the expansion of a catheter balloon.

All of the dependent claims of this application respectively depend from one of the three independent claims, which each provide the patentable distinction discussed above. It is submitted that Follmer et al. fails to provide any further teaching in this area which might render the claims of this application obvious, in view of any failure to provide a teaching of the last three lines of any of the independent claims of this application.

Carlblom is cited for the concept that polyolefin is a "gas-permeable material". While this is acknowledged to be true, the examiner is urged to note, once again, that this teaching fails to provide added weight to the rejection relative to any teaching of the last three lines of any of the independent claims 1, 6, or 11. Thus, it is submitted that claims 1, 6, and 11, and their dependent claims, are patentable over this rejection.

Claims 1-16 have been rejected by the examiner as unpatentable over Shimada et al., Burns et al., and Rydell, as previously discussed with respect to claims 11-14, further in view of Carlblom and Follmer et al.

It is submitted that the distinction of claims 1-16 is the same as previously discussed. The defect of the rejection is a failure to make obvious the last three lines of any of independent claims 1, 6, and 11.

As such, it is submitted that the claims of this application are patentable.

New claims 18 and 19 are clearly supported by the disclosure of this application.

The examiner is urged to note the Information Disclosure Statement that was filed on June 11, 2004. It is requested that the references cited therein be reviewed and considered.

In view of the above, allowance of the claims is respectfully requested.

Respectfully submitted,

SEYFARTH SHAW LLP

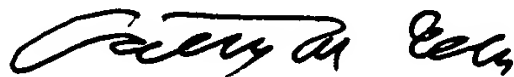


Garrettson Ellis
Registration No. 22,792
Attorney for Applicant

SEYFARTH SHAW LLP
55 East Monroe Street, Suite 4200
Chicago, Illinois 60603
(312) 269-8567

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Registered Attorney for Applicant
Date: August 9, 2004